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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,730	UCHIYAMA ET AL.	
	Examiner	Art Unit	
	Jonathan G. Cwern	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *52-62* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 July 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/24/04,4/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-51 in the reply filed on 7/14/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 52-62 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/14/08.

Drawings

The drawings are objected to because: In Figure 5b, the label "5c" appears to be incorrect. In Figure 6a, the label "71" appears to be incorrect. In Figure 16, reference characters L, U, R, and D are not described in the specification. Also, Figures 18a and 18b appear to be described in the specification, however the specification refers only to a Figure 18. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered

and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

On page 32, line 24, the word "juggling" should be "jiggling".

On page 44, line 8, it appears that Figure "15" should probably be Figure "16".

On page 51, line 6, Figure 18 is referred to, however there is no Figure 18 in the drawings. There is however a Figure 18a and 18b present in the drawings, but not described in the specification. This section most likely refers to those Figures, and should be corrected appropriately to address them.

Appropriate correction is required.

Claim Objections

Claims 1-51 are objected to because of the following informalities:

In claim 1, "the body cavity" lacks antecedent basis.

In claim 1, 4, 10-11, 13-14, 18, and 49 it is unclear what is meant by the term "arranged to".

In claims 2-3, 5, 15-17, 20-21, 27, 29-31, 34-35, 41, 45, and 47, it is unclear what further structure has been set forth.

In claim 3, "the change amount" lacks antecedent basis.

In claims 4 and 10, "the side surface" lacks antecedent basis. And it is unclear which side is being referred to, if the structure is a cylinder shape.

In claim 4 and 10, "the substantially cylindrical shaft" lacks antecedent basis, it is earlier referred to as "a cylindrical shaft".

In claim 4 and 10, "the magnetic pole" lacks antecedent basis.

In claim 4 and 10, "the direction substantially orthogonal" lacks antecedent basis.

In claim 4 and 10, "magnetic pole detection means" is an improper form of means + function language.

In claim 4 and 10, "the rotating magnetic field" lacks antecedent basis.

In claim 5, "the thrust generating amount" lacks antecedent basis.

In claim 7, "the current state" and "the advancing direction" lack antecedent basis.

In claim 11, "the side surface" lacks antecedent basis. And it is unclear which side is being referred to, if the structure is a cylinder shape.

In claim 11, "the cylindrical shaft" lacks antecedent basis.

In claim 13, "image rotation correction means" and "display means" are improper forms of means + function language.

In claim 17, "the change amount" lacks antecedent basis.

In claim 19, "image rotation correction means" is an improper form of means + function language.

In claim 20, "the rotating frequency" lacks antecedent basis.

In claims 22 and 23, "the capsule medical apparatus" lacks antecedent basis.

In claim 23, "the end portion" lacks antecedent basis, and it is unclear what end is being referred to.

In claim 24, "magnetic pole detection means" is an improper form of means + function language.

In claim 24, the last two sentences are confusing and appear to be grammatically incorrect, "changes the information providing unit referred to".

In claim 26, "the current state" and "the advancing direction" lack antecedent basis.

In claim 31, "the change amount" lacks antecedent basis.

In claim 33, "image rotation correction means" is an improper form of means + function language.

In claim 34, "the rotating frequency" lacks antecedent basis.

In claim 37, "the end portion" lacks antecedent basis, and it is unclear what end is being referred to.

In claim 38, "magnetic field detecting means" is an improper form of means + function language, and lacks antecedent basis, in claim 10 it is referred to as "magnetic

pole detection means", which would also be an improper form of means + function language.

In claim 38, the last two sentences are confusing and appear to be grammatically incorrect, "changes the information providing unit referred to".

In claim 40, "the current state" and "the advancing direction" lack antecedent basis.

In claim 46, "the current state" and "the advancing direction" lack antecedent basis.

In claim 50, "magnetic pole detection means" is an improper form of means + function language.

In claim 50, the last two sentences are confusing and appear to be grammatically incorrect, "changes the information providing unit referred to".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, it is unclear as to how an input unit can instruct a thrust generating direction. How can a direction be instructed? In claims 6, 25, 39, and 51, it is unclear as to what "the operation" is referring to, and it is unclear as

to what "the operation amount" is. These terms also lack antecedent basis. In claims 13-14, 18-19, 32-33, and 49, it is unclear what the term "allocates the operating direction" refers to. Also, this term lacks antecedent basis. In claims 24, 38, and 50, it is unclear what the term "the control history" refers to. Also, this term lacks antecedent basis.

Regarding claim 12, the use of the term "any" implies that all of the components, a magnetic field generating device, an electric field generating device, and a motor can be present in the invention at the same time. However, the disclosure seems to indicate that "any one" of those components would be in the invention.

Regarding claims 8, 28, 42, and 48, the phrase "such as" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 sets forth that the medical apparatus main body is inserted in the body cavity, thereby including the patient as part of the claimed invention. The patient should not be included as part of the claimed invention, this is non-statutory subject matter.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 12/055142. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be an obvious modification to detect the direction of the medical apparatus using magnetic fields.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-18, and

65-68 of copending Application No. 10/910738. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be an obvious modification generate thrust so as to cause the endoscope body to rock about an axis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, and 9-27 of copending Application No. 11/823598. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be an obvious modification to design the device to meet specific criteria such as a diameter-reduced portion or the spiral structure disposed inside the main body.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-51 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8-24, and 26-29 of copending Application No. 11/230201. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be an obvious modification to select a specific speed for the thrust generation.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9-12, 14-18, 20-27, 29-32, 34-41, 45-47, and 49-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiyama et al. (Spiral-type Micro-machine for Medical Applications, 2000 International Symposium on Micromechatronics and Human Science, IEEE, 2000) in view of Strommer et al. (US 6233476) and Takizawa et al. (US 2003/0020810).

Ishiyama et al. disclose a spiral-type magnetic micro-machine. The device comprises a magnet and a spiral blade which can be controlled by a rotational magnetic field. The rotation generates forward or backward thrust by the spiral blade based on the rotational plane of the field. The swimming direction of the machine can therefore be controlled by changing the direction of the rotational magnetic field. Also, the velocity of the device can be controlled by changing the frequency of the field (page 65-68). While no explicit mention is made of an input unit or control unit, these are inherent, as something must be inputting the data to change the direction and frequency of the magnetic field. Input units are well known in the art and are capable of inputting any sort of data which could aid in the control of the device, such as the strength or direction of the magnetic field, in order to move the device a desired distance at a desired speed. Ishiyama et al. fail to show a storing unit or direction detecting unit and that the device is a medical apparatus inserted in the body cavity.

Strommer et al. disclose a medical positioning system. Strommer et al. teach the use of a storage unit and direction detecting unit. A location and orientation detector can detect the device, and store this data in the storage unit (column 13, line 49-column 14, line 38 and column 16, lines 14-23).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have detected the direction of the device as taught by Strommer et al., in the system of Ishiyama et al. Ishiyama et al. discuss navigating the device through a maze, by changing the direction of the device. While no mention is made of how the direction of the device is detected, it would be an obvious modification to

include a direction detecting unit so as to control and maneuver the device as desired, with an understanding of its location. Furthermore, it would be obvious to include a storage device. Storage devices can be used to store a variety of data, such as image data or positional data.

Takizawa et al. disclose a capsule-type medical apparatus. Takizawa et al. teach the use of capsule type devices for medical systems. Takizawa et al. use a similar spiral design with magnetic field to move the device. The device further includes imaging means as is common in capsule-endoscope devices ([0159]-[0181]).

It would have been obvious to have modified or used the device of Ishiyama et al. as a medical apparatus in a patient as taught by Takizawa et al. Indeed, Ishiyama et al. note that their device shows great potential for running in human organs (page 68).

It would be an obvious design choice to one of ordinary skill in the art to position the magnet in the capsule, either at the end or at the center of gravity. Takizawa et al. teach that the magnet is positioned at the end of the capsule, however it would be an obvious design choice to one of ordinary skill in the art to position the magnet anywhere in the capsule so long as it does not negatively impact the use of the device.

Claims 13, 19, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiyama et al. (Spiral-type Micro-machine for Medical Applications, 2000 International Symposium on Micromechatronics and Human Science, IEEE, 2000) in view of Strommer et al. (US 6233476) and Takizawa et al. (US 2003/0020810) as applied to claims 3-4 and 10 above, and further in view of Frassica (US 5989230).

Frassica discloses a rotate to advance catheterization system. Frassica teaches that the image can be corrected for rotation for easier viewing (column 1, lines 30-35).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the combined device of Ishiyama et al., Strommer et al., and Takizawa et al. to have corrected the image for rotation in order to provide a benefit to the person administering the procedure, by allowing the image to be more easily viewed.

Claims 8, 28, 42, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiyama et al. (Spiral-type Micro-machine for Medical Applications, 2000 International Symposium on Micromechatronics and Human Science, IEEE, 2000) in view of Strommer et al. (US 6233476) and Takizawa et al. (US 2003/0020810) as applied to claims 1, 4, 10, and 11 above, and further in view of Yokoi et al. (US 2003/0023150).

Yokoi et al. disclose a capsule-type medical device and medical system. Yokoi et al. teach that a capsule-type device can be configured to deliver medicine, or to suck up body fluid ([0184]-[0186]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the combined device of Ishiyama et al., Strommer et al., and Takizawa et al. to deliver medicine or extract body fluid as taught by Yokoi et al. This is a common use of such capsule-type endoscopes, as they are in direct

proximity to the organ which requires medicine, and thus are in a convenient position to deliver the medicine which is required for treatment.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiyama et al. (Spiral-type Micro-machine for Medical Applications, 2000 International Symposium on Micromechatronics and Human Science, IEEE, 2000) in view of Strommer et al. (US 6233476) and Takizawa et al. (US 2003/0020810) as applied to claim 11 above, and further in view of Iddan (US 2002/0111544).

Iddan discloses a system and method for determining in vivo body lumen conditions. Iddan teaches the use of a motor to drive a motion producing device ([0043]).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the combined device of Ishiyama et al., Strommer et al., and Takizawa et al. to use a motor to drive the device as taught by Iddan. There are a variety of methods well known in the art for moving a capsule within a patient, and any of those, including motion from a propeller driven by a motor, would be a suitable equivalent to the motion driving mechanisms of Ishiyama et al.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ishiyama et al. (Spiral-type Micro-machine for Medical Applications, 2000 International Symposium on Micromechatronics and Human Science, IEEE, 2000) in view of

Strommer et al. (US 6233476) and Takizawa et al. (US 2003/0020810) as applied to claim 11 above, and further in view of Ouchi (US 6527705).

Ouchi discloses a fully swallowable endoscopic system. Ouchi teaches the use of an external power supply, and a device in the capsule which receives the signal from the power supply and delivers the power to the components within the capsule (column 7, lines 7-37).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have modified the combined device of Ishiyama et al., Strommer et al., and Takizawa et al. to use an external power supply as taught by Ouchi, in order to reduce the size of the device by eliminating a bulky power supply. This also can be safer for the patient in the case of the capsule becoming stuck inside. Techniques for providing power from devices external to the patient are well known in the art, and it would be obvious to modify a capsule type device to use any sort of power supply system which appropriately powers the device.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737